

510 (k) SUMMARY

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Device Name: Fluid Resistant Eyeshield Mask
Classification Name: MASK, SURGICAL

- Predicate Device(s):
1. Tecno! Fluid Resistant Surgical Mask, 510 (k) #K874608, dated December 2, 1987.
 2. 3M Fluid Resistant Mask, 510 (k) #K910110, dated March 20, 1991

Device Description:

The Fluid Resistant Eyeshield Masks are constructed of a light weight spunbonded polyolefin or cellulosic outer facing, a meltblown polyolefin filter media, and a light weight spunbonded polyolefin or cellulosic inner facing. The three layers of the mask body are collated and sonically welded around the edges to enclose the filter media. The bodies have either light weight polyolefin or cellulosic nonwoven material sonically welded or otherwise attached to both sides of the body (ties on the surgeons tie masks) or polyolefin/elastic earloops sonically welded or otherwise attached to both sides of the body. The masks have a malleable aluminum wire encapsulated in the facing to form the mask to fit the nose. An optical quality eyeshield is attached to the mask by ultrasonic welding.

All of the materials used in the construction of the masks are being used in other currently marketed devices, such as our regular surgical mask, 510 (k) #K801036.

These masks filter particles at an average efficiency of greater than 95% when tested at both 1.0 micron and 0.1 micron particle sizes. The breathability of the masks (measured by the pressure drop across the mask) averages no more than 5.0 mm of water.

All of the materials used in the construction of the mask are used in other currently marketed devices, these include:

- American Threshold Surgical Mask 510(k) #K801036
- Tecno! Surgical Mask 510(k) #K874608
- 3M Surgical Mask 510(k) #K910110

Statement of Intended Use:

This product is intended for use in infection control practices to minimize contamination caused by exhaled microorganisms and reduce the potential exposure of the wearer to blood and body fluids.

Testing Submitted to Determine Substantial Equivalence and Device Claims:

1. Water Resistance, Impact Penetration Test, Nelson Laboratories SOP#MBG/037
-This procedure is designed to measure the resistance of materials to water penetration under contact with sprayed water. This test was performed to demonstrate substantial equivalence.
2. Differential Pressure, Delta P Test, Nelson Laboratories SOP#ARO/006
-The differential pressure test determines the air exchange differential of porous materials and is important for determining the breathability of surgical face masks. This test was performed to demonstrate substantial equivalence.
3. Latex Particle Challenge, Nelson Laboratories SOP#ARO/011
-This procedure provides for evaluation of non-viable particle retention or filtration efficiency of barrier materials. This test was performed to substantiate device claims.

Conclusions Drawn from the Results of the Above Testing:

1. Water Resistance, Impact Penetration Test Results:

American Threshold Fluid Resistant Mask:

-Average per-cent increase in blotter weight = 2.64% increase in the first study and 9.15% in the second.

Tecnol Fluid Resistant Mask:

-Average per-cent increase in blotter weight = 49.33% increase in the first study and 2.99% in the second.

2. Differential Pressure, Delta P Test Results:

American Threshold Fluid Resistant Mask:

-Differential Pressure average was 2.19 in the first study and 2.54 in the second.

Tecnol Fluid Resistant Mask:

-Differential Pressure average was 1.99 in the first study and 2.68 in the second.

3. Latex Particle Challenge Test Results:

American Threshold Fluid Resistant Mask: (with or without eyeshield)

-Average filtration efficiency for Polyolefin Inner Facing:

1.0 micron particle size = 99.3% filtration efficiency

0.1 micron particle size = 98.4% filtration efficiency

-Average filtration efficiency for Cellulosic Inner Facing:

1.0 micron particle size = 99.2% filtration efficiency

0.1 micron particle size = 99.2% filtration efficiency

Based on the above test results American Threshold Industries considers their fluid resistant mask to be substantially equivalent to the other fluid resistant masks currently on the market.